Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparative Effectiveness of Auditory, Visual, and Vibrotactile Sensory Cueing Versus Sham on Tibialis Anterior Muscle Onset Latency During Gait Initiation in Community-Dwelling Older Adults: A Sham-Controlled Crossover Trial

Protocol summary

Study aim

evaluate the effect of auditory, visual, and vibrotactile sensory cues on neuromuscular preparation during gait initiation in community-dwelling older adults, using a within-subject crossover design

Design

Randomised, sham-controlled, within-subject crossover trial with five experimental conditions (auditory, visual, vibrotactile, sham, self-initiated), 42 participants, Latin square randomisation with concealed allocation, blinded outcome assessment and data analysis, single-centre study.

Settings and conduct

This study will be conducted in the Biomechanics Laboratory at the University of Tabriz, in a single session with 10 trials of each condition. Data collectors will not be blinded; the outcome assessor and data analyst will be fully blinded. Participants will be blinded to the sequence of stimuli.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Age ≥ 65 years, Independent ambulation without the use of assistive devices, No history of falls during the previous year, Ability to stand, unsupported for at least 30 seconds, Ability to walk 7 metres independently, Right-foot dominance Exclusion Criteria: Neurological disorders, Musculoskeletal disorders affecting gait or balance, Peripheral neuropathy, Hearing loss > 25 dB, Visual impairment

Intervention groups

Intervention group: Community-dwelling older adults who will receive an auditory stimulus (750 Hz, 70 dB, 200 ms), a visual stimulus (green, 200 ms, distance of 7m), and a vibrotactile stimulus (80 Hz, 1.5 times the detection threshold). Comparison group: Community-dwelling older adults who will receive a sham stimulus (sub-threshold, 0.2 times threshold) and a self-initiated condition (without any stimulus).

Main outcome variables

Tibialis anterior and medial gastrocnemius onset latency, centre-of-pressure parameters, co-activation

General information

Reason for update

Preliminary pilot observations indicated that requiring older adults to attend five separate sessions with a 24–48-hour interval between sessions was practically demanding for this age group and substantially increased the risk of participant attrition across sessions. Furthermore, given that older adults typically do not maintain consistent physical or daily conditions across different days of the week, conducting the protocol across multiple separate sessions increased the risk of confounding factors (such as day-to-day medication changes, or fluctuations in physical status) influencing the results between sessions. Therefore, to reduce participant attrition and eliminate potential confounding effects arising from the time interval between sessions, it was decided to modify the study protocol from five separate sessions to a single laboratory session, while keeping the randomised sequence of experimental conditions (Latin square design) unchanged.

Acronym

IRCT registration information

IRCT registration number: **IRCT20260627069971N1**
Registration date: **2026-07-17, 1405/04/26**
Registration timing: **prospective**

Last update: **2026-07-27, 1405/05/05**
Update count: **1**

Registration date

2026-07-17, 1405/04/26

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-07-23, 1405/05/01

Expected recruitment end date

2026-08-06, 1405/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative Effectiveness of Auditory, Visual, and Vibrotactile Sensory Cueing Versus Sham on Tibialis Anterior Muscle Onset Latency During Gait Initiation in Community-Dwelling Older Adults: A Sham-Controlled Crossover Trial

Public title

Comparing the Effects of Sound, Light, and Vibration on Gait Initiation in Older Adults

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age ≥ 65 years Community-dwelling Independent ambulation without assistive devices No falls during the previous year Ability to stand unsupported for 30 seconds Ability to walk 7 meters independently Right-foot dominant

Exclusion criteria:

Neurological disorders Musculoskeletal disorders Peripheral neuropathy Hearing loss > 25 dB Visual impairment Use of medications known to affect motor performance (benzodiazepines, antipsychotics, antidepressants, antiparkinsonian agents)

Age

From **65 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **42**

More than 1 sample in each individual

Number of samples in each individual: **50**

Each participant will complete 10 trials in each of the five experimental conditions (auditory, visual, vibrotactile, sham, and self-initiated) during a single laboratory session; consequently, a total of 50 trials will be recorded for each participant (10 trials × 5 conditions = 50 trials).

Randomization (investigator's opinion)

Randomized

Randomization description

This study will be designed as a crossover trial, and each participant will experience all five experimental conditions. Because the four externally cued conditions (auditory, visual, vibrotactile, and sham) require order balancing, a 4 × 4 Latin square design will be used as the block randomization method. This design will ensure that each of the four conditions occupies each of the four sequence positions (first through fourth) an equal number of times, thereby controlling for order and carry-over effects. The self-initiated condition, since it will serve solely as a descriptive reference, will always be performed after completion of the other four conditions and will not be included in the randomization sequence. The unit of randomization will be the individual; that is, each participant will be independently allocated to one of the four Latin-square sequences. Stratified randomization will not be used in this study. The random sequence will be generated using the online software Randomization.com. This will be carried out by an investigator who will not be involved in outcome assessment. The four allocation sequences derived from the Latin square design will be pre-determined. For allocation concealment, each participant's sequence number will be placed in opaque, sequentially numbered, sealed envelopes, which will be opened in the order in which participants enter the study; in this way, the intervention sequence for each individual will remain concealed until the start of the testing session. The outcome assessor (the individual analyzing the EMG and COP data) and the statistical analyst will be kept blinded to each participant's allocation sequence throughout the study.

Blinding (investigator's opinion)

Single blinded

Blinding description

This study will employ partial blinding. Participants will be blinded to the sequence of the four externally cued conditions (visual, auditory, vibrotactile, and sham), as this sequence will be concealed through the 4 × 4 Latin square design and sealed envelopes, so that participants will not know the upcoming condition prior to each session. However, participants will not be blinded to the nature of the intervention at the moment it is delivered, except in the vibrotactile condition: because the auditory (audible tone) and visual (visible light) stimuli are inherently and overtly perceptible, participants will immediately recognize whether the stimulus received was auditory or visual; complete participant blinding to these two interventions is therefore not achievable. Only in the vibrotactile condition, due to the active sham

design at a sub-threshold intensity (0.2 times the individual detection threshold), will participants be unable to reliably distinguish the active stimulus from sham, allowing for meaningful blinding. The principal investigators and data collectors will not be blinded, owing to the perceptible nature of the auditory, visual, and vibrotactile stimuli at the time of administration, but will follow a standardized protocol. Both the outcome assessor and the data analyst will be fully blinded; condition labels will be replaced with random codes by an independent researcher, and analysis will be conducted on de-identified data. A data and safety monitoring board will not be established, and the manuscript authors will have access only to the final analyzed data.

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of University of Tabriz

Street address

29 Bahman Boulevard, Tabriz, East Azerbaijan Province, Iran

City

TABRIZ

Province

East Azarbaijan

Postal code

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Approval date

2025-12-28, 1404/10/07

Ethics committee reference number

IR.TABRIZU.REC.1404.206

Health conditions studied

1

Description of health condition studied

Age-related decline in neuromuscular preparation during gait initiation and increased fall risk in community-dwelling older adults.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Tibialis anterior muscle onset latency relative to the sensory stimulus (visual, auditory, vibrotactile, or sham) during gait initiation, in milliseconds

Timepoint

During a single laboratory session, immediately following each trial; 10 consecutive trials of each of the four experimental conditions (visual, auditory, vibrotactile, sham) will be recorded.

Method of measurement

Tibialis anterior muscle electrical activity will be recorded using surface electromyography. Bipolar electrodes will be placed on the skin, according to the SENIAM protocol, at one-third of the distance between the fibular head and the medial malleolus, with a 20-mm inter-electrode distance; the reference electrode will be placed over the tibial tuberosity. Signals will be sampled at 2000 Hz, band-pass filtered at 20–450 Hz, full-wave rectified, and then smoothed. Muscle onset will be identified using the Teager–Kaiser Energy Operator algorithm and defined as the first point exceeding 3 standard deviations above baseline for at least 25 milliseconds following delivery of the sensory stimulus. Automated onset detection will be verified by a trained assessor blinded to the experimental condition.

Secondary outcomes

1

Description

medial gastrocnemius muscle onset latency relative to the sensory stimulus (visual, auditory, vibrotactile, or sham) during gait initiation, in milliseconds

Timepoint

During the laboratory session, immediately after each trial, for each of the four experimental conditions (visual, auditory, vibrotactile, sham)

Method of measurement

Surface electromyography of the medial gastrocnemius muscle will be recorded. Bipolar electrodes, according to the SENIAM protocol, will be placed over the most prominent point of the medial gastrocnemius muscle belly, parallel to the muscle fibre direction; the inter-electrode distance will be 20 mm. Signals will be sampled at 2000 Hz, band-pass filtered at 20–450 Hz, processed using the Teager-Kaiser energy operator, and then smoothed with a fourth-order zero-lag Butterworth filter. Muscle onset will be defined as the first point exceeding 3 standard deviations above baseline for at least 25 milliseconds following delivery of the sensory stimulus (visual, auditory, vibrotactile, or sham).

2

Description

Trial-to-trial variability (standard deviation) of tibialis anterior onset latency, in milliseconds.

Timepoint

Calculated after completion of all valid trials for each participant in each of the four conditions (visual, auditory, vibrotactile, and sham), at the end of the laboratory session.

Method of measurement

The standard deviation of tibialis anterior onset latency values will be calculated separately for each participant and each of the four conditions (visual, auditory, vibrotactile, and sham). For this purpose, the onset latency of tibialis anterior muscle activity (based on surface electromyography data) will first be recorded for each individual valid trial within that condition; the standard deviation of these values across the valid trials of that condition will then be calculated using the standard sample standard deviation formula (the square root of the variance, i.e., the mean of the squared differences between each value and the mean of that condition's trials, divided by the number of trials minus one). This value will be treated as an index of trial-to-trial variability; smaller values will indicate greater temporal consistency of the neuromuscular response under that condition.

3

Description

Time of onset of posterior displacement of the center of pressure (COP) relative to sensory stimuli (visual, auditory, vibrotactile, sham), in milliseconds

Timepoint

During the single laboratory session, immediately following each trial, for each of the five experimental conditions (visual, auditory, vibrotactile, sham).

Method of measurement

Recorded using a force plate (1000 Hz sampling rate, 10 Hz low-pass filter); Center of Pressure onset is defined as the first sample at which posterior Center of Pressure onset velocity exceeds a threshold of 3 standard deviations above baseline for at least 20 milliseconds following delivery of the sensory stimulus (visual, auditory, vibrotactile, or sham).

4

Description

Magnitude of posterior center of pressure (COP) displacement during the anticipatory postural adjustment (APA) phase, in centimetres.

Timepoint

During the anticipatory postural adjustment (APA) phase: from the onset of centre-of-pressure displacement to completion of its posterior displacement. For each trial and each of the five experimental conditions (visual, auditory, vibrotactile, sham, and self-initiated). This measurement will be conducted during a single laboratory session, with 10 repetitions of each condition.

Method of measurement

Force plate (1000 Hz sampling rate, 10 Hz low-pass filter); posterior center of pressure displacement will be calculated from the point of center of pressure onset to the point of completion of posterior displacement (end of the anticipatory postural adjustment phase), and will be reported in centimetres.

5

Description

Peak posterior center of pressure velocity during the anticipatory postural adjustment (APA) phase, in centimetres per second.

Timepoint

During the anticipatory postural adjustment (APA) phase: from the onset of center of pressure displacement to completion of its posterior displacement. for each trial and each of the five experimental conditions (visual, auditory, vibrotactile, sham, and self-initiated). This measurement will be conducted during a single laboratory session, with 10 repetitions of each condition.

Method of measurement

Force plate (1000 Hz sampling rate, 10 Hz low-pass filter); posterior centre-of-pressure (COP) velocity during the anticipatory postural adjustment phase (from the point of centre-of-pressure onset to completion of posterior displacement) will be calculated by differentiating centre-of-pressure position data; the maximum value of this velocity will be recorded as the peak posterior centre-of-pressure velocity and reported in centimetres per second

6

Description

Step latency (time from cue onset to foot-off), in milliseconds.

Timepoint

During the single laboratory session, immediately following each trial, for each of the four experimental conditions (visual, auditory, vibrotactile, sham).

Method of measurement

Recorded using a force plate; the moment of complete separation of the dominant foot (toe-off) from the force plate surface is defined as the first sample at which the vertical ground reaction force falls below a pre-specified threshold of 10 N; the time interval from cue presentation to this point will be calculated as the step latency.

7

Description

First-step length, in centimetres

Timepoint

Immediately after completion of the first step in each trial, for each of the five experimental conditions (visual, auditory, vibrotactile, sham, and self-initiated).

Method of measurement

First-step length will be measured using a graduated ruler/scale mounted on the laboratory floor; the linear distance between the posterior edge of the heel of the stance (supporting) foot and the posterior edge of the heel of the stepping foot at the moment of initial ground contact will be calculated. This measurement will be recorded by an assessor blinded to the experimental condition.

8

Description

Tibialis anterior–medial gastrocnemius (TA–MG) co-activation index during the anticipatory postural

adjustment phase, for each of the five experimental conditions (visual, auditory, vibrotactile, sham, and self-initiated), expressed as a percentage.

Timepoint

During a single laboratory session, immediately following each trial; 10 trials of each of the five experimental conditions will be recorded.

Method of measurement

The co-activation index will be calculated using the Falconer–Winter method, based on raw surface EMG signals from the tibialis anterior and medial gastrocnemius muscles; the formula is: two times the minimum of the mean TA and MG EMG amplitudes, divided by the sum of the mean TA and MG EMG amplitudes, multiplied by 100. Higher values indicate greater simultaneous agonist–antagonist muscle activation.

Intervention groups

1

Description

Intervention group: The auditory stimulus will consist of a 750-Hz pure tone generated using Cool Edit Pro software (Version 2.1; Syntrillium Software Corporation) and saved as a 44.1-kHz, 16-bit WAV file. The stimulus will be delivered binaurally through insert earphones (E-A-RTONE 3A; Etymotic Research, Elk Grove Village, IL, USA) at an intensity of 70 dB sound pressure level (SPL). Stimulus duration will be 200 ms with 5-ms rise and fall times. The stimulation delay from the electronic trigger will be 5 ± 1 ms. Each participant will receive this stimulus across 10 trials, presented in a randomised order.

Category

Other

2

Description

Intervention group:The visual stimulus will consist of illumination of a green light panel (LED; wavelength 525 nm, dimensions 20 × 20 cm), which will be installed 4 meters in front of the participant, at the end of the 7-meter walking path (approximate visual angle of 1.5 degrees). Ambient room illumination will be maintained at 300 lux (measured at the participant's eye level), and participants requiring corrective lenses will be required to wear them during testing. The illumination duration will be 200 milliseconds, and the stimulus delivery delay from the electronic trigger will be 15 ± 1 milliseconds. Each participant will receive this stimulus across 10 trials, presented in a randomised order.

Category

Other

3

Description

Intervention group: Vibrotactile stimulation will be delivered using an array of four miniature vibration motors (Precision Microdrives 310-101; diameter 8 mm, thickness 3.4 mm; manufactured by Precision Microdrives, UK), arranged within a 3 × 3 cm area and positioned approximately 3 cm proximal to the right Achilles tendon. The motors will produce an 80-Hz vibration for 200 milliseconds (with 10-millisecond rise and fall times). Stimulation intensity will be individually determined for each participant using a staircase procedure; the mean detection threshold will be 0.18 mm, and experimental stimulation will be delivered at 1.5 times the individual detection threshold. The stimulus delivery delay from the electronic trigger will be 10 ± 2 milliseconds. Each participant will receive this stimulus across 10 trials, presented in a randomised order.

Category

Other

4

Description

Control group: The sham condition will be delivered using an identical array of four vibration motors (same model and anatomical location as the active vibrotactile condition), with the difference that the motors will be activated at an intensity of 0.2 times the individual detection threshold (a sub-threshold, imperceptible intensity). The sound pressure level generated by the motors will be measured using a calibrated sound level meter (Brüel & Kjær Type 2250); at active intensity it will be 32 dB at a distance of 10 cm, and at sham intensity 28 dB, both below the ambient laboratory noise level (34 dB). Before the protocol begins, participants will be informed: 'You may or may not feel a vibration. Some people notice it, whereas others do not.' They will also be asked to respond to the cue regardless. Each participant will receive this stimulus across 10 trials, presented in a randomised order.

Category

Other

5

Description

Control group: In the self-initiated (control) condition, participants will voluntarily initiate gait at a time of their own choosing within a 10-second response window, without receiving any external sensory cue. This condition will always be performed after completion of the other four conditions and will serve solely as a descriptive reference.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Local Community Centres in Tabriz

Full name of responsible person

sina najafpoor

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Sponsors / Funding sources

1

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Department of Biomechanics and Motor Control, University of Tabriz
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

De-identified Individual Participant Dataset — Sensory Cueing and Gait Initiation Trial: This dataset will include all primary and secondary outcome variables recorded at the individual level: tibialis anterior onset latency, medial gastrocnemius onset latency, onset latency variability, centre-of-pressure parameters (onset time, posterior displacement, peak velocity), step latency, first-step length, and baseline demographic variables (age, sex, body mass index, MoCA score, frailty status). The co-activation index, as an exploratory variable, will also be included in this dataset but will be explicitly labeled as "exploratory." All direct and indirect participant identifiers will be removed prior to publication. Full Study Protocol: The complete study protocol, including inclusion and exclusion criteria, detailed description of interventions, randomization and allocation concealment methods, and the pre-specified outcome measurement plan. Statistical Analysis Plan: Full specification of the pre-specified statistical models (linear mixed-effects models, Benjamini-Hochberg adjustment, BCa bootstrap), data quality criteria, and pre-planned sensitivity analyses. R Statistical Analysis Scripts: Complete R code (including the lme4, lmerTest, and boot packages) to reproduce all primary, secondary, sensitivity, and exploratory analyses reported in the manuscript. Informed Consent Form: A blank, de-identified template of the informed consent form used in this study (the form template only, not completed participant forms).

When the data will become available and for how long

The access period for de-identified data, analysis scripts, and supplementary materials will begin immediately upon final acceptance of the manuscript for publication. These materials will be accessible via a Digital Object Identifier (DOI), included in the published article, hosted in the public Zenodo repository, and this access will continue for a minimum of 10 years from the date of publication. During the peer review process (prior to final acceptance), materials will be made available through the corresponding author upon reasonable request.

To whom data/document is available

Because the data and documents from this study will be deposited publicly and without access restrictions in the Zenodo repository, they will be available to any researcher — whether affiliated with academic institutions, research centres, or industry — whose intended use is legitimate scientific research, replication of findings, or meta-analysis, without requiring specific permission from the authors. The only requirement will be appropriate citation of the original data source (the published article and repository DOI).

Under which criteria data/document could be used

In addition to the criteria described above regarding who is eligible to request access, the following conditions will govern the use of data and documents from this study: 1. Purpose of use: Data may be used solely for non-commercial research purposes; any commercial use will require separate written permission from the corresponding author. 2. Permitted types of analysis: No restrictions will be placed on the type of statistical analysis or research methodology applied to the delivered data; researchers may use any analytical approach appropriate to their research objectives. 3. Request process: Applicants must submit a written request to the corresponding author, including the project title, research objectives, proposed methodology, and a written commitment to adhere to research ethics principles. 4. Data delivery mechanism: Upon approval of the request, data will be provided to the applicant either through the public Zenodo repository (using the dedicated DOI) or via direct file transfer. 5. Citation requirement: Researchers will be required to properly cite the data source, including the DOI and reference to the original article, in any publication resulting from secondary use of the data. 6. Participant privacy protection: Applicants will be required to commit to using the data solely for the purposes stated in their request and to refrain from any attempt at re-identification of participants.

From where data/document is obtainable

First priority (public and direct access): All de-identified data, analysis scripts, and supplementary materials will be deposited in the public Zenodo repository and will be accessible via the Digital Object Identifier (DOI) included in the published article. Applicants may download the data free of charge by following the DOI link in the article, without needing to contact the authors directly. Second priority (request to the corresponding author): For supplementary information or documents not deposited in the public repository (e.g., the informed consent form), applicants may submit a written request — including the project title, research objectives, proposed methodology, and a written commitment to research ethics principles — to the corresponding author. Corresponding author contact information: Name: Hamed Fadaei Affiliation: Department of Sports Pathology and

Biomechanics, Faculty of Sport Sciences, Kharazmi University, Tehran Postal address: 15719-14911 Email: hamed.fadaei1371@gmail.com Phone: 09025527109

What processes are involved for a request to access data/document

Applicants should first access the public Zenodo repository via the Digital Object Identifier (DOI) provided in the article and download the data directly and free of charge, a process expected to take less than 5 minutes. If access to the repository is not possible, the applicant must submit a written request — including the project title, research objectives, proposed methodology, and a commitment to adhere to research ethics principles — by email to the corresponding author. The request will be reviewed within 3 to 7 business days, and if approved, the data will be provided to the applicant within 1 to 3 business days via an access link, email, or secure file-sharing platforms. The total time required, in cases where the public repository is not accessible, will be approximately 1 to 2 weeks.

Comments